REMARKS

The present communication responds to the Final Office Action of March 24, 2009, in which the Examiner rejected claims 1-6, 8, 9, 12, 13, 17 and 19 and objected to the specification. Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,575,939 ("Brunel"). Claim 13 was rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 6,258,068 ("Kirchhofer"). Claims 17 and 19 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 4,444,560 ("Jacklich"). Claims 1-5 were rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of U.S. Patent 5,433,352 ("Ronvig"). Claim 8 was rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of Ronvig and further in view of U.S. Patent 4,850,967 ("Cosmai").

Claims 1, 13 and 17 have been amended. No new subject matter has been added to the claims. Support for the amended claims can be found in the specification at least as follows:

Claim 1: page 11, lines 27-28; page 12 and Figs. 2a, 2b, 2d, and 3.

Claim 13: page 17-18 and Figs. 6-8.

Claim 17: page 12 and Figs. 2a, 2b, 2d, and 3.

The claim rejections and objections are addressed and/or traversed in view of the amendments and for at least the reasons articulated below.

Specification

The disclosure was objected to for failure to provide proper antecedent basis for the claimed subject matter.

The Examiner states that the specification does not disclose a "distal end" of the piston rod. While this terminology would be clearly understood by one of ordinary skill in the art, claim 1 has been amended to conform the claim language to the precise words used on page 11, lines 27-28, of the specification.

The Examiner also states that "[t]he specification fails to disclose the releasing element projecting radially outward from inside the casing. OFFICE ACTION at 2. Description of this feature is, however, provided in the specification on page 16-17: "[S]uch a rotary mechanism is operated in accordance with the invention using *a releasing element which projects*, in the form of a lever 23, *in the radial direction from the injection device. The lever 23 projects outwards through an opening 24 in the casing 3 of the injection device.*" (emphasis added) Additional support is provided in Fig. 5.

Withdrawal of the objections to the specification is requested.

Rejection under 35 U.S.C. § 102

The rejections are traversed for at least the following reasons.

Brunel

Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as anticipated by Brunel. However, Brunel does not disclose or suggest the following features recited in claim 6.

"wherein the releasing element projects radially outward from inside the casing and extends through an opening in the casing of the injection device"

The Examiner incorrectly asserts that Figs. 2, 8, 9, 11-13, and 16 depict a releasing element (trigger 15) that projects radially outward from inside the casing. Office Action at page 3. To the contrary, the Brunel trigger 15 is formed as an integral part of sleeve 12 that projects longitudinally in alignment with the surface of the sleeve 12. See Figs. 2, 8, 9, 11-13. Only ribs 16 formed on the surface of trigger 15 "project[ ] with respect to the peripheral wall of the sleeve 12." Brunel, column 6, lines 11-13. However, even including ribs 16, trigger 15 does not project radially outward *from inside the casing* as required by claim 6. Instead, trigger 15 is part of the casing.

The Examiner further incorrectly asserts that trigger 15 "extends through the opening (shown at 17 in Fig. 2, also see lines 1-16 of column 6)." Office Action at page 3. In fact,

element 17 is "a slot provided in the peripheral wall" of sleeve 12 that is provided to form ("delimit") the trigger 15 in the surface of sleeve 12. Brunel, column 6, lines 1-2. Trigger 15 does "extend through" slot 17, but is instead formed by it.

Thus, Brunel does not disclose or suggest the claimed releasing element that projects radially outward from inside the casing and extends through an opening in the casing of the injection device.

wherein "dimensions of said opening limit movement of the releasing element, thereby setting the predetermined amount of the dosage"

Brunel does not disclose or suggest this claimed functionality in which the dimensions of the opening in the casing through which the releasing element radially extends determines the amount of the dosage to be dispensed by the device. In fact, Brunel does not disclose any dose-setting means. The function of the Brunel device is to "assure[s] . . . the complete emptying of the syringe." Brunel, column 9, lines 13-14. Thus, there is no disclosure or suggestion of a mechanism to "set" a predetermined dosage because the only dosage in Brunel is the entire contents of the pre-filled syringe.

The Examiner mistakes the locking-unlocking functionality of the opening 31 (including cutouts 32), which prevents trigger 15 from actuating the injection unless the trigger is properly aligned with the opening (see Figs. 14-15 and column 8, lines 60-64), for the claimed dosage determining functionality of the opening through which the releasing element radially extends. Neither the trigger 15 nor the opening 31 in Brunel has any effect on the dosage dispensed by the device. Therefore, Brunel does not disclose or suggest this feature of the claimed releasing element.

"wherein the predetermined amount of the dosage is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side"

Brunel does not teach the claimed first and second stoppers, wherein the releasing element releases the predetermined dosage when the element is moved from the first to the second stopper, each located on opposite sides of the opening in the casing through which the releasing mechanism radially extends. The Examiner suggests that opening 31 performs this function but does not identify what structure is asserted to forms the claimed stoppers. In fact, Brunel does not disclose or suggest the claimed first and second stoppers.

For at least the preceding reasons, claim 6 is patentable over Brunel.

Claims 9 and 12 depend directly or indirectly from claim 6 and are patentable over Brunel for at least those reasons set forth above with respect to claim 6.

Reconsideration and withdrawal of the § 102 rejection of claims 6, 9 and 12 are requested.

Kirchhofer et al.

Claim 13 was rejected under 35 U.S.C. § 102(b) as anticipated by Kirchhofer. However, Kirchhofer does not disclose or suggest the following features recited in amended claim 13.

"wherein the holder for the product container together with the sleeve are insertable into the casing prior to delivery of an injection and removable from the casing after the injection delivery to enable replacement of the product container"

Kirchhofer does not disclose or suggest an injection device wherein the product container together with the needle protecting sleeve are insertable into and removable from the casing of the device to enable replacement of the product container. Instead, Kirchhofer teaches a container holder 30 that is "connected to the front housing sleeve 7 non-shiftably" by screwing the holder to the housing sleeve. Kirchhofer, column 5, lines 19-22. Thus, the Kirchhofer product holder is not insertable and removable with respect to the casing. Furthermore, there is no description in Kirchhofer to suggest that the needle safety sleeve 10 is removable from the casing, or that the combination of the holder and safety sleeve together are insertable and

removable. Consequently, Kirchhofer does not disclose or suggest this feature recited in amended claim 13.

"wherein the needle cap together with the injection needle are removable from the casing after delivery of the injection to enable replacement of the needle cap and injection needle with an unused needle cap and injection"

Kirchhofer also does not describe a device in which the needle cap and injection needle together are removable to enable replacement with an unused cap and needle. The Kirchhofer needle cap is removable with respect to the needle to enable use of the device and can be re-positioned onto the device to protect the needle after use. Kirchhofer, however, does not describe replacement of the needle or the removal of the needle and cap together as recited in amended claim 13.

For these reasons, amended claim 13 is patentable over Kirchhofer. Reconsideration and withdrawal of the § 102 rejection of claim 13 are requested.

Jacklich

Claims 17 and 19 were rejected under 35 U.S.C. § 102(b) as anticipated by Jacklich. However, Jacklich does not disclose or suggest the following features recited in amended claim 17.

"wherein the operating means includes a one-piece lever comprising a lever arm and a protrusion projecting from the lever arm at a fixed angle substantially perpendicular to the lever arm towards a longitudinal axis of the injection device"

The operating means described in Jacklich is an operating handle 53 coupled to a ratchet 57 that "is pivoted on handle 53." Jacklich, column 2, line 25. The angle between the ratchet 57 and handle 53 is variable. There is no teaching or suggestion in Jacklich of the recited one-piece lever comprising a lever arm and a protrusion projecting from the lever arm at a fixed angle substantially perpendicularly to the lever arm.

Notably, the Examiner considers both ratchet 57 and pawl 65 to be the claimed protrusion (Office Action at 4 and 8). However, the protrusion recited in amended claim 17 is "co-operative with dispensing means via a surface oblique with respect to a longitudinal axis of the device, such that the dispensing means is moved in an axial direction relative to the device by pivoting the operating means." Thus, the claimed protrusion is utilized to move the dispensing means. Pawl 65 does not perform this claimed function, but is only provided to prevent return motion of the piston rod. Jacklich, column 2, lines 37-8. Therefore, pawl 65 is not comparable to the claimed protrusion. Also, while ratchet 57 advances the piston rod in Jacklich, ratchet 57 does not render obvious the claimed operating means as discussed above.

"wherein the releasing element projects radially outward from inside the casing through an opening in the casing of the injection device, and dimensions of the opening limit movement of the releasing element, thereby determining the dosage amount to be dispensed"

The Examiner asserts that ratchet 57 constitutes both the claimed protrusion of the operating means and the claimed releasing element, which are recited as two different components of the claimed injection device. Office Action at 7-8. For the reasons discussed above, the claimed operating means is patentably distinct from ratchet 57.

The claimed releasing element is also patentably distinct from ratchet 57 because ratchet 57 does not extend through an opening in the casing that limits the movement of the ratchet, thereby determining the dosage amount to be dispensed as recited in amended claim 17. The dimensions of groove 49 into which ratchet 57 is biased by spring 55 do not determine the dose amount to be dispensed. Therefore, Jacklich does not teach or suggest the claimed opening through which the releasing means extends having dimensions that determine the dose amount to be released.

"wherein the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side"

The ratchet teeth asserted by the Examiner to be the first and second stoppers (Office Action at 7-8) are not located on opposite sides of the claimed opening in the casing as recited in amended claim 17. Therefore, Jacklich does not disclose or suggest the claimed first and second stoppers located on opposite sides of the claimed opening.

For these reasons, amended claim 17 is patentable over Jacklich.

Claim 19 depends directly from claim 17 and is patentable over Jacklich for at least those reasons set forth above with respect to amended claim 17.

Reconsideration and withdrawal of the § 102 rejection of claims 17 and 19 are requested.

Rejections under 35 U.S.C. § 103(a)

The rejections are traversed for at least the following reasons.

Jacklich in view of Ronvig

Claims 1-5 were rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of Ronvig.

However, neither Jacklich or Ronvig discloses or suggests the claimed operating means formed as a **one-piece lever** comprising a lever arm and **a protrusion that projects from the lever arm at a fixed angle substantially perpendicular to the lever arm towards a longitudinal axis of the injection device**.

Both Jacklich and Ronvig teach operating mechanisms wherein the portion actuating the piston rod extends from the longitudinally extending handle portion at a variable angle as the device is actuated. In Jacklich, the ratchet 57 pivots on handle 53 of lever 11 as the lever is operated by the user. Jacklich, column 2, lines 24-27. In Ronvig, the dispenser "comprises a U-shaped lever arm" that" in its resting position . . . forms an angle relative to the top surface of the lever . . . [wherein] depression of the lever arm 22 toward housing 1 causes a reduction of said

angle until the top surface of the lever arm 22 reaches a position where the two parts are substantially parallel, as shown best in FIG. 6." Ronvig, column 3, lines 50-66. Thus, neither Jacklich or Ronvig, or the combination thereof, discloses or suggest the claimed operating means. Amended claim 1 is therefore patentable over the asserted combination of references.

Claims 2-5 depend directly from amended claim 1 and are patentable over the combination of Jacklich and Ronvig for at least those reasons set forth above with respect to amended claim 1.

Applicant requests that the rejection of claims 1-5 under § 103(a) over Jacklich in view of Ronvig be withdrawn.

Jacklich in view of Ronvig and further in view of Cosmai

Claim 8 was rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich and Ronvig as applied to claim 5 above, and further in view of Cosmai. However, Cosmai fails to remedy the fundamental disclosure deficiencies of Jacklich and Ronvig as discussed above. Therefore, claim 8 is patentable over the asserted combination of references.

Conclusion

This response should be entered pursuant to 37 C.F.R. §116 because it presents the rejected claims in better form for consideration on appeal.

The application now stands in allowable form, and reconsideration and allowance are respectfully requested.

This paper is being submitted on or before July 24, 2009, and an extension of the time to respond until that date is requested. The required fee should be charged to Deposit Account No. 04-1420. No additional fees should be due in connection with this paper, but the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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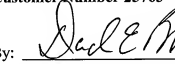
Date: July 23, 2009

By: 
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